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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,146	01/11/2002	Bhushan Patwardhan	059012/282083	6629

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 10/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,146	PATWARDHAN ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 35-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>0203</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election of Group III claims 19-34, in the August 8, 2003 response is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 19-34 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rendered vague and indefinite by the phrase "A composition obtained from Withania Somnifera characterized as" because this phrase fails to adequately define the essential element of the invention – i.e., that the composition is an extract composition which is obtained from the recited plant. It is, therefore, suggested that the term --extract-- be inserted before the word "composition" in this phrase. However, please note that the term "extract" ("extract composition"), in and of itself, does not adequately delineate its metes and bounds. This term is best defined as a product-by-process since product-by-process claims are intended to define products which are otherwise difficult to define (and/or distinguish from the prior art - see, e.g., the art rejections below). It is well accepted in the herbal art that extraction, or a series of extractions, with one of various distinct solvents has a profound impact on the final product with

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respect to the presence, absence, amounts, and/or ratios of active ingredients therein and, thus, its ability to provide the desired functional effect(s) instantly claimed and/or disclosed. Since the extract (i.e., an extract composition obtained from *Withania somnifera*) itself is clearly essential to the claimed invention, the step(s) by which the claimed extract is obtained are also clearly essential and, therefore, must be recited in the claim language itself (i.e., as a product-by-process). Please note that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., *In re Van Guens*, 988 F.2d 1181, 26 PSPG2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention. It is suggested that independent claim 19 be rewritten as a product by process (e.g., via the transitional phrase --whereby the extract composition is obtained by: ...--) which recites the essential steps used in preparing the instantly disclosed extract - e.g., via the steps recited on page 37, lines 25-31 of the instant specification (including reciting Markush groups which clearly define the essential solvents used in each fractionation step - e.g., for Fraction A: -- extraction ... with a medium polar solvent selected from the group consisting of acetone, tetrahydrofuran, and ethyl acetate--) to overcome this rejection.

Also in claim 19, the phrase defined by elements (b) and (c) are not grammatically correct and, thus, are somewhat unclear. It is suggested that the term --being-- be inserted at the beginning of the (b) and (c) phrases. Also, the term "having" within the context of defining element (d) of claim 19 is vague and indefinite because it is unclear if this term is open or closed language with respect to defining "at least one glycowithanolide". It is suggested that this term be replaced by --comprising--.

Claims 32 and 34 recite the limitation "the subject" in line 1 of each. There is insufficient antecedent basis for this limitation in these claims. Based upon the overall claim language of claims 31 and 33, from which these claims respectively depend, it is suggested that the phrase be changed to --the Balb-c mouse--. Please note that the phrase "subject mass" (recited in claims 31 and 33) does not provide adequate antecedent basis for --the subject-- within the context of the overall claim language of these claims.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 22, 24, 25, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal et al. (Phytother. Res., 1989).

A composition obtained from *Withania somnifera* having immune-stimulating and/or anti-tumor activity, is water soluble, is substantially free of alkaloids, and has at least one glycowithanolide such as sitoindoside IX or X is apparently claimed.

Ghosal et al. teach a composition obtained from *Withania somnifera* having immune-stimulating and anti-tumor activity which contains sitoindoside IX or X, is free of alkaloids, and which is inherently water soluble (e.g., is dissolved in buffered saline) – see entire document.

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Please note that the functional effects with respect to increasing white blood cells in a mouse if such a composition were administered thereto (e.g., claims 31-34) would be inherent to the immune-stimulating, anti-tumor composition taught by Ghosal et al.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-34 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ghosal (US 6,153,198) or over Patwardhan (US 5,494,668).

Each of the cited references disclose an extract composition obtained from *Withania somnifera* which appear to be identical to the presently claimed composition, since each of the reference extract compositions are apparently comprised of the same or similar levels of ingredients as instantly claimed, were produced in a manner similar to that instantly claimed, and also demonstrate one or more of the instantly claimed functional effects - e.g., immunostimulating and/or anti-tumor activity, water-soluble, substantially free of alkaloids, and expressly or intrinsically contains more than one glycowithanolide (including sitoindoside IX and/or X) therein (see, e.g., US '198: col 1, line 29 – col 2, line 67; col 3, lines 49-60; col 6, Table 2; col 9, line 60 – col 10, line 50, and claims; US '668: col 1, line 50 – col 2, line 9; col 5, line 14 – col 6, line 25; col 10, line 11 – col 11, line 8, cols 12-13, Example 1, and claims).

In the alternative, even if the claimed *Withania somnifera* composition is not identical to the referenced *Withania somnifera* extract compositions with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced *Withania somnifera* extract compositions is/are likely to inherently possess the same characteristics of the claimed composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 U.S.C. § 103

Claims 19-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal et al. (Phytother. Res., 1989), in view of Ghosal (US 6,153,198) or Patwardhan (US 5,494,668).

The references are relied upon for the reasons set forth above.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include one or more of the ingredients (within the claimed ranges) taught by the secondary references within the immune-stimulating and/or anti-tumor *Withania somnifera* composition taught by the Ghosal et al. 1989 reference (e.g., further including one or more additional glycowithanolides therein, having glycowithnolide and/or ash content within the claimed ranges, as well preparing an extract composition which would intrinsically have the same or similar TLC and/or HPLC profile(s) as those instantly claimed - including via incorporating one or more of the preparatory process steps disclosed by these references) based upon the beneficial teachings provided therein with respect to such working conditions.

Accordingly, the result-effective adjustment of these types of conventional working conditions (including adjusting the various proportions and/or amounts of advantageous ingredients within such immunostimulating, anti-tumor *Withania somnifera* extract compositions) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Again, please note that the functional effects with respect to increasing white blood cells in a mouse if such a composition were administered thereto (e.g., claims 31-34) would be intrinsic to such *Withania somnifera* extract compositions.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.



Christopher R. Tate
Primary Examiner, Group 1654